K060756

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BMC IT Health Solutions

5. Summary 510(k)

Submitter: BMC Gesellschaft für Medizintechnik mbH
Harburger Schlossstrasse 6-12
D-21079 Hamburg - Germany

Contact Person: Dr. Angelika Berger
Managing Director
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1. Identification of Device

Proprietary-Trade Name: MEDLOG
Classification Name: MWI
Common/Usual Name: Data Collection Software

2. Equivalent legally marketed device

This product is similar in design and identical in funtion to the DataCaptor Software, K032142. The premarket notfication adds compatibility with basic capabilities of DataCaptor.

3. Indications of Use (intended Use)

The MEDLOG System is indicated for the use in data collection and clinical information management. MEDLOG is connected with independent bedside or clinical devices either directly or through networks.

MEDLOG is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices, which is connected to.

4. Description of Device

MEDLOG is based of open-architecture design using JAVA Technology. MEDLOG is a data acquisition and distribution software. It retrieves data from serial or network devices and makes thes data available over networks or any other type of communication for us in software applications. BMC customers can buy cables and can connect the devices directly to the COM Port or they can use a multiport box. Customers also can use Serial/Ethernet converters if needed. BMC not recommends hardware suppliers. MEDLOG enables the interfacing of medical devices, which are types of blood-gas analyzers or cardiac-monitoring systems. It is a matter of principle, that MEDLOG is able to support other kind of connected devices.
The basic componente of MEDLOG ist the MCS Communication server, which runs and controls MMD Device Drivers. The collected device data can stored temporarily my MCS. The MEI External Interfaces makes data available for other external systems.

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5. Safety and Effectiveness, comparison to predicate device

Comparion Areas	***DataCaptor, K032142***	***BMC MEDLOG***
Indications of Use	The MEDLOG System is indicated for the use in data collection and clinical information management. MEDLOG is connected with independent bedside or clinical devices either directly or through networks. MEDLOG is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices, which is connected to.	SAME
Interfaces	Serial or network	SAME
Where used	Hospitals	SAME
Computer	Windows PC	SAME

6. Conclusion

In all important respects, the MEDLOG Data Acquisition and Distribution Software is substantially equivalent to the DataCaptor Software K032142. The main difference between the two is, that MEDLOG is with JAVA Technology and DataCaptor is with Windows/DCOM Technoloy. DataCaptor supports more connected devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 2006

BMC Gesellschaft fur Medizintechnik mbH
c/o Dr. Angelika Berger
Managing Director
Harburger Schlossstrasse 6-12
D-21079 Hamburg - Germany

Re: K060756
Trade Name: MEDLOG Model 1-0-10
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotarhometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 18, 2006
Received: October 20, 2006

Dear Dr. Berger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B/Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060756

Device Name: MEDLOG, MODEL 1-0-10

Indications For Use:

The MEDLOG System is indicated for the use in data collection and clinical information management. MEDLOG is connected with independent bedside or clinical devices either directly of through networks.
MEDLOG is not intended for monitoring purposes, nor is the software intended to control any of the clinical devices, which is connected to.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060756